A WHITE PAPER ON PRESCRIPTION DRUGS:

A Comprehensive Review of Problems That Face Washington State Residents and Recommendations for the Future

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AN INTRODUCTORY MESSAGE FROM COMMISSIONER SENN

Over the past decade, prescription drug expenditures have continued to increase at a rate of almost 15 percent per year, and currently account for over 10 percent of total health care spending, exceeding $90 billion. While drugs consumed about 5.6 percent of our health dollar in 1962, this percentage is expected to exceed 18 percent by 2008.

Although drug access is in the headlines today, it is not a new issue for the Office of the Insurance Commissioner. Since I first took office in 1993, we have moved on a variety of fronts.

For example, drug coverage has been a major issue for the 75,000 seniors thrown out of their Medicare managed-care plans over the past three years. Again this year, our Statewide Health Insurance Benefits Advisors (SHIBA) HelpLine program will hold hundreds of Medicare assistance clinics around the state, helping these beneficiaries recover their lost benefits – including drug coverage.

We have worked with seniors and disabled consumers with medication-screening programs that let pharmacists see that different medications are not working against each other. Washington also was the first state in the nation to adopt an off-label drug rule, which applies universally to all serious illnesses.

Today's report really has its roots in 1996, when we undertook the first comprehensive review of Washington state's prescription drug coverage as part of a bipartisan effort to survey the state's health insurance carriers and examine the possibility of increasing access to prescription drug benefits. That survey also sought to stimulate industry interest in an individual stand-alone prescription drug benefit, one that could be purchased to supplement other health coverage.

Over the past two years, my office has been working to improve the way carriers disclose their drug coverage to consumers. This is vital, because consumers need to know what their drug formulary is and how it changes as time passes. We currently are refining new rules that will require insurers to answer a series of common questions about the drug coverage in specific plans.

As we continue to seek change that will benefit consumers, we also must recognize that drugs, perhaps more than any other aspect of the medical system, have improved health outcomes in recent years. Furthermore, the issue is not merely one of access and cost control. Our solutions also must deal with questions of appropriate use, provider and consumer education, and system efficiency.

To fully address these problems we also must go beyond the power of one state agency and engage even more resources. That is why this year's effort began with a series of hearings across the state this spring to hear from seniors, the disabled, and other persons who were having difficulty obtaining the drugs they need. I also directed my Health Policy staff to study the causes of the problem, and we contracted with the University of Washington School of Pharmacy to analyze the drug coverage in a cross-section of health insurance policies.

A successful effort to address this problem will take a commitment from all of us: policy makers, insurers, providers, manufacturers, and citizens. I present this white paper as a framework for this important work.

DEBORAH SENN
Washington State Insurance Commissioner

EXECUTIVE SUMMARY

I. Rising costs and shrinking benefits have squeezed drug coverage access for many seniors and the disabled.

- From 1993 to 1998, prescription drug expenditures increased from $50.6 billion per year to $93.4 billion per year. U.S. spending on drugs accounts for nearly 10 percent of total health care spending now, and this figure may exceed 18 percent by 2008.

- In general, prescription drugs make up about one-sixth of all health spending by the elderly, but with some senior groups it approaches one-third. Proportionately, the elderly spend nearly twice as much out-of-pocket for prescription drugs than younger people.

- Most Americans (70%) do not understand that Medicare does not include drug coverage. In fact, only 53 percent of Medicare beneficiaries nationally had any kind of drug coverage in 1999, and the poorest beneficiaries have the lowest rate of coverage. Even beneficiaries with coverage still pay an average of one-third of their drug bills out of pocket.

- Below age 65, nearly one in four Americans have no coverage for prescription drugs. This figure is likely to grow as fewer employers offer health benefits and more employers try to cut their costs. Future retirees will be among the first to feel these cutbacks, and the number of U.S. seniors is growing substantially: By 2010, the 54-to-64 age group will increase by 59 percent.

- Total drug spending for Medicare beneficiaries with drug coverage is nearly two-thirds higher than those without coverage. But individually, those without coverage pay nearly twice as much out-of-pocket (an average of $463 versus $253).

II. Seniors and the disabled testified at our hearings that they have had to resort to a series of desperate measures to access the drugs they need.

- **Skipping doses/Splitting pills** — Some seniors testified that they work out a system to skip certain doses – every fourth or fifth prescribed pill, for example. Although skipping doses stretches their drug dollar, it can hinder the purpose of the drug and possibly be dangerous. Others, armed with kitchen knives or plastic pill splitters, try to break up large-dose pills into pieces that will stretch their drug dollars.

- **Provider factors** — Some doctors have quietly helped seniors by insisting companies allow more cost-effective 120-day or six-month prescriptions. Other physicians have helped cut costs by "diagnosing" a covered condition that can be treated with the same medication the uncovered condition actually requires.

- **Impoverishment** — Despite lifetimes of self-sufficiency, many seniors today are forced into assistance programs like Medicaid when their prescription drug bills grow beyond their means. Sadly, some Washington state seniors have been forced out of retirement and into menial jobs in order to absorb the high cost of prescription drugs on a fixed income.

III. The roots of the crisis include the unprecedented success of today's drug treatments, rising public expectations, and the enormous amounts of money required to develop new drugs.

- The life expectancy of an American was 45 in 1900, 54 in 1920, 70 in 1965, and around 76 today. With the advancement in genetics, it could reach 95 by 2025. Much of this improvement in health status is associated with drug development.

- These successes have created an expectation that whatever the ailment, there eventually will be some form of medical intervention—most often a drug—that will restore our health. In addition, today's consumer expects advanced treatments to be covered by insurance, even when its medical necessity is questionable. Because drugs are mostly paid for by third parties, consumers are seldom aware of their true costs.

- Drug companies have been very profitable ranking first on all three Fortune 500 profit indices—return on revenue, assets, and equity. The industry is highly subsidized by government, but it also faces unique problems: Drug development time has grown from an average of 8.1 years in the 1960s to 14.9 years.

- Drug pricing is so complicated as to be deemed inscrutable, which treats consumers inequitably and hamstrings appropriate purchasing strategies.

- The industry pegs the average cost of developing a drug at more than one-half billion dollars. But critics point to a significant expense — $8.3 billion a year – that the industry uses for drug advertising to doctors and consumers.

RECOMMENDATIONS

Solutions to the problems of drug access need to be comprehensive and systematic, not piecemeal, and should follow a firm set of policy principles. We have defined these principles to include:

1. Consumers: Solutions must focus on improving citizens' health status, be integrated into broader health care strategies, be based on medical efficacy and efficiency, and prohibit discrimination based on sex, health need, and method of treatment. Ideally, solutions will enhance consumers' knowledge of the system and help them make appropriate decisions about their own health, for which they are fundamentally responsible.

2. The health industry: They also should encourage the appropriate responsibility among insurers, purchasers, manufacturers, and government, and regulatory limits should not unduly hinder the private drug manufacturing industry from developing appropriate medications and treatments in the future. The cost of drugs should be made explicit. Similarly, adequate public resources must be found to protect those unable to purchase the drugs they need.

3. Health-care providers: Solutions to drug access must permit health providers to fully participate in their patients' care within their scope of practice, consistent with medical efficacy.

KEY ACTIONS

Any overall plan to address the problems of drug coverage access and expense must include three levels of activity.

- Federal changes are necessary because many of the factors that face Washington seniors and disabled are national in scope and beyond the reach of state mandates.
- State-level change by the Governor and Legislature is necessary and timely, too, because some parts of the problem can be addressed most efficiently here.
- Finally, the Office of the Insurance Commissioner, as the primary overseer of the insurance industry, can lead the way to some solutions with regulatory change.

I. The President and Congress Should:

I. Establish a federal drug program for seniors

II. Assist states in establishing pharmacy assistance programs and cost saving efforts

III. Permit interstate Medicaid/Medicare purchasing cooperatives

IV. Direct federal health agencies to develop “no-nonsense” strategies to enhance appropriate drug use among providers and consumers

V. Develop guidelines for pricing strategies that will assist state bulk-purchase systems

VI. Enhance the safety of drug use and reduce medical errors

2. Our Governor and the Legislature Should:

I. Establish a comprehensive pharmacy management task force, the result of which should be the development of strategies for appropriate pricing, purchasing and use of drugs.

II. Create a pharmacy assistance program

III. Consider entering into a compact with other states to purchase drugs for state programs and low-income persons

IV. Consider a state consolidated drug purchasing program

V. Eliminate discrimination in drug coverage by passing legislation like the contraceptive drug coverage and mental health parity bills

VI. Establish a comprehensive drug education program

3. The Insurance Commissioner Will:

I. Require insurance companies to fully disclose drug benefits

II. Prohibit sex or other group discrimination in formulary design

III. Establish an appropriate role for consumers in drug benefit design

IV. Study and develop methods to establish parity in drug dispensing between local pharmacy and mail order organizations

V. Enhance the role of pharmacists and other under-utilized health providers in patient education and demand and disease management

VI. Guarantee that health plan drug benefits offer a full range of drugs, including generic, formulary, and off-formulary drugs, consistent with appropriate enrollee cost participation.

Full recommendations are listed in Appendix A.

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I. THE CRISIS

The crisis, simply put, is: Significant rises in the cost of drugs, in tandem with the decline of drug benefits.

The Rising Cost of Drugs:

From 1993 to 1998, prescription drug expenditures in the United States increased from $50.6 billion per year to $93.4 billion per year, presently rising at a rate of 15 percent. Currently drugs account for nearly 10 percent of total health care spending. This trend will yield an 18 percent share in 2008. For certain groups of seniors, drugs consume 30 cents of their health care dollar.

The following table shows the growth in drug costs as a percentage of over-all health expenditures.

Figure 1: National Health Expenditures: Annual Percentage Growth, 1992-1997

	1992	1993	1994	1995	1996	1997	5-year average
Total	**9.1%**	**7.4%**	**5.5%**	**4.9%**	**4.9%**	**4.8%**	**5.5%**
Hospital Care	8.2	5.8	3.9	3.4	3.9	2.9	4.0
Physician Services	8.5	5.7	3.8	4.6	3.3	4.4	4.3
Nursing Home	9.0	6.7	7.0	6.2	5.2	4.3	5.8
Prescription Drugs	10.6	8.7	9.0	10.6	13.2	14.1	11.1

Source: HCFA National Health Expenditure data, 1997

Declining Drug Benefits:

Since the elderly and disabled are higher users of drugs and since their major source of insurance coverage - Medicare - does not have drug benefits, they bear the brunt of the problem. However, about one quarter of the non-Medicare population is also without drug coverage. The U.S. Department of Health and Human Services released a comprehensive survey of drug coverage in April 2000. The following are some of the key findings of that work.[1] Please note some of these data are drawn from 1996; it is safe to assume that the problem has worsened in the last few years.

Figure 2: Current drug coverage

- Only 53 percent of Medicare beneficiaries had drug coverage for the entire year of 1996.
- Most sources of drug coverage are potentially unstable. Almost 48 percent of beneficiaries with drug coverage through Medigap and 29 percent who were covered through Medicare HMOs had drug coverage for only part of the year.
- Drug benefits are becoming less generous. There is considerable evidence that cost sharing for prescription drugs is increasing and that overall caps on coverage are becoming both more common and are being set at lower levels.
- Drug coverage is likely to decline as fewer employers offer health benefits to future retirees. For example, one employer survey recorded a drop from 40 percent in 1993 to 28 percent in 1999 in the number of large firms offering health benefits to Medicare-eligible retirees. Additionally, employers have tightened eligibility rules and increased cost shifting to retirees.
- Beneficiaries with incomes between 100 percent and 150 percent of poverty have the lowest rate of coverage.
- Beneficiaries are less likely to have coverage if they are very old or live outside of a metropolitan area.
- Medicare beneficiaries with coverage fill nearly one-third more prescriptions than those without coverage.
- Although total drug spending for beneficiaries with coverage is nearly two-thirds higher, those without coverage pay nearly twice as much out-of-pocket ($463 versus $253).
- On average, beneficiaries with coverage pay out-of-pocket for about one-third of the total expenditure for their drugs.
- Drug insurance makes an especially large difference in dollar terms for those in the poorest health. Among beneficiaries with five or more chronic conditions, those with coverage had much higher total spending ($1,402 versus $944) and much lower out-of-pocket spending ($412 versus $944) than beneficiaries without coverage.
- Individuals without drug coverage pay a higher price at the retail pharmacy than the total price paid on behalf of those with drug coverage. The differences generally held up when examining the Medicare and non-Medicare populations.
- Cash customers (with or without coverage) pay more for a given drug than those with third-party payments at the point of sale.

Coverage in Our State:

To get a better understanding of what is available through insurance in Washington, the University of Washington School of Pharmacy was asked to analyze the drug coverage in the polices of several of our largest carriers.[2]

The study's findings point out that:

- **One of the** eight surveyed plans required subscribers to pay for the medication and then submit the bill for reimbursement. Others depended on copayments at the pharmacy counter. Only one of the plans had an annual deductible for coverage.

- **All of the plans** use cost incentives to encourage subscribers to shift from brand-name drugs to less-costly generic drugs.

- **Eight of the plans** restrict coverage for fertility drugs or hair-growth stimulants; seven for weight-loss aids, anti-wrinkle creams, and erectile dysfunction drugs; six for coverage of human growth hormone for uses not approved by the U.S. Food and Drug Administration; five for coverage of some naturopathic remedies or onychomycosis; four do not cover contraceptives. Access to restricted drugs is made available by "prior authorization" to encourage appropriate use.

- **Some plans** allow subscribers to expand their drug coverage by purchasing separate riders that add options to their formularies.

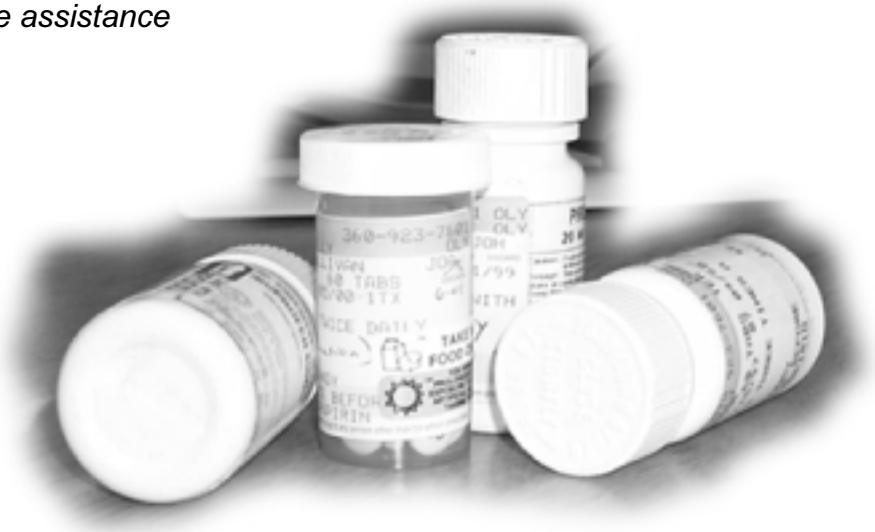
- **The study** also noted that travelers may face problems with plans that require prescription purchases at specified pharmacies. Five of the eight plans have this requirement. Two of the plans do not provide coverage for prescriptions written by nonparticipating providers.

- **Although many** pharmacists are knowledgeable and could provide efficient disease management information and guidance, none of the plans utilize this resource for concerns like emergency contraception, influenza vaccine, or diabetes education. (All eight plans provide diabetes education in non-pharmacy settings, as required by law.)

- **All of the surveyed** plans included on-line adjudication of claims, but frequent breakdowns or poor communication between pharmacies and the health plans frustrate many consumers from getting timely information about their coverage.

Who Are the Faces Behind these Statistics?

The Office of the Insurance Commissioner held hearings around the state in April, May and June of 2000 to listen to ordinary people's concerns about prescription drugs. The testimony was often moving, sometimes poignant, and inevitably tinged with resignation. Without state assistance and changes, a growing number of Washington citizens know they will find themselves without access to this critical area of health-care.



James, Vancouver: A Teamsters Union retiree, James currently is covering an annual $7,000 prescription drug bill, most of it required by his wife's kidney cancer. Although he has some coverage in his retirement, it caps at $2,000, and to cover the remainder, he's had to return to part-time employment shagging grocery shopping carts in a parking lot. "To pay for these prescriptions we're faced with, I've taken a part-time job, at 76 years old, (to) round up them stray carts. My income last year…offset about what my prescription costs…It isn't easy, but I have to do it." A complicating irony: Because of Medicare's requirements, the sympathetic grocery store cannot add him to its prescription drug plan without jeopardizing his Teamster's plan. "I can't carry them both."

Ruth, Seattle: She polled the other residents of her retirement complex and found an average prescription drug bill of $375 a month. "The majority of people are not insured." One person pays $150 a month; others are as high as $10,000 a year. "They would have to give up their homes and rent, or not do the necessary repairs on their homes." Ruth works as a volunteer AARP counselor and knows that some aid is available, but adds, "Many people who are eligible for (Medicaid), they fill the forms out and mail them into DSHS but a lot of people who work for DSHS that do the screening, they don't even know about some of the programs and they don't understand these programs, and a result the (applicants) get discouraged dealing with the bureaucracy there and they just give up."

Nicholas, Seattle: Nicholas was one of 29 Seattle-area residents who accepted a television station's offer to bus them to Canada in hopes of finding cheaper drug prices. "Twenty-nine of us saved a total of $12,900 that afternoon. Personally, my six-month American prescription bill is about $1,800 (after my HMO discount); these drugs cost me $789 in Canada, a savings of about $1,000. That is 57% of my usual cost.…There are various remedies proposed and being debated in Congress – by Democrats, by Republicans…None is adequate."

Victoria, Tacoma: A heart-transplant patient, she has insurance coverage but a prescription drug bill that ranges between $1,500 and $2,000 a month. Cyclosporin, the most expensive of her medications, cost only $754 in January 1995, but earlier this year cost $1,032. “This is the same drug, the patent has expired. It’s not even a cutting-edge drug…But it’s keeping me alive, and I’m concerned that I’m going to outlive my ability to pay for this medication.” She said most consumers are headed for the same dilemma. “On the one hand, I’m at the mercy of the pharmaceutical companies, who are interested in their bottom line. They feel they have a responsibility to their shareholders….On the other hand, the insurance companies are saying they’re losing and they have a responsibility to their shareholders. And I’m in the middle, with medications that I can’t do without, the price continues to rise, and somebody out there needs to find a way to make sure that they continue to be affordable….within my ability to pay for them.”

Robert, Seattle: Robert is a non-Hodgkins lymphoma patient who underwent chemotherapy for three and a half years. “As a result, I have a very depleted immune system which leaves me vulnerable to infections. I also have full-blown, insulin-dependent diabetes as a result.” He and his wife take several drugs regularly, with an annual prescription drug bill between $6,000 and $7,000, and none of it is covered by either Medicare or Premera Blue Cross’ Medigap policy. “With our resources dwindling as they are, needless to say we are one hundred percent in favor of drug coverage under Medicare.”

Kathleen, Spokane: She takes two medications normally combined in a single pill, but her plan’s formulary doesn’t cover the combination pill, and she would have to acquire them separately. One is only available in a pill four times the dosage she requires, so she would have to split “a pill smaller than my little fingernail four ways.” Her plan covers the other medication’s generic equivalent, but “it is so different from the one I take that it is like telling a young woman who aspires to be an Olympia gold medalist in figure skating, ‘I’m sorry. We don’t cover figure skating. We do cover, however, peewee hockey, so you go over to peewee hockey, and I’m sure you’ll achieve your goal of a gold medalist in figure skating.’ Just because they’re both done on ice, doesn’t mean they’re the same.” Her prescription drug bill runs to $200 a month above what her insurance covers. She said seniors have a number of desperate measures to deal with drug prices: “Find somebody who is real old and feeble who takes the same medicine and if they die you can have the rest of their pills and that will cover you for at least a month. Another one is the pill-splitting. Another is….about skipping doses. You figure out how often you can skip a dose without its really hurting you. Some medications, they say it’s every third dose. With others, it’s every fourth. They skip doses!”

II. THE CAUSES

While there appears to be some consensus that there is a crisis, there is a heated debate over the causes. The following are the ones frequently cited. The degree to which existing research can enlighten this debate varies.

The Success of an Industry:

A basic question one must ask when reviewing this trend is “Is this 18 percent really that bad a thing?” If drugs are that successful, why shouldn’t we spend that much on them? Haven’t they reduced hospitalizations and the need for many types of surgeries? Haven’t they increased independence and worker productivity? While few will accept unbridled drug cost rises, many will agree that the contribution of drugs to health, especially life expectancy, has been significant. The life expectancy of an American was 45 in 1900, 54 in 1920, 70 in 1965, and is around 76 today. With the advancement in genetics, it could reach 95 by 2025. Most analysts would attribute earlier gains to advances in public health, i.e. clean water, effective sanitation, food inspections, etc. However, it is also believed that the advancements of recent decades are strongly associated with the burgeoning of new and effective drugs.

The drug manufacturers’ trade association, PhRMA, is quick to point out that antibiotics and vaccines figured importantly in the near eradication of syphilis, diphtheria, whooping cough, polio, and measles. Likewise, cardiovascular drugs, ulcer therapies, and anti-inflammatories have had a major impact on heart disease, ulcers, emphysema, and asthma.

Please note that one must be cautious with these conclusions, because causation is always a contentious endeavor.

Advances in biomedical science are helping researchers develop novel approaches to attack infectious, chronic, and genetic diseases. New knowledge and novel research techniques in biochemistry, molecular biology, cell biology, immunology, genetics, and information technology are transforming the process of drug discovery and development.

Now that the human genome is mapped, a myriad of potential new targets for pharmaceutical innovation will be identified. Currently, only about 500 distinct targets exist for drug interventions. That figure is expected to increase 6- to 20-fold, to as many as 10,000 drug targets, in the near future.

Already more than 60 new biological therapeutics and vaccines have been approved by the Food and Drug Administration (FDA) and are on the market. And more than 60 million patients worldwide have been helped by medicines produced through biotechnology.

Public Expectations:

The success of the medical system, and drugs in particular, has created an expectation that whatever the ailment, there eventually will be some form of medical intervention—most often a drug—that will restore our health. This argument is most striking when analyzed in light of public health prevention. It has been clearly demonstrated that the real causes of most of what makes us sick or kills us—heart disease, cancer, and stroke—are associated with life-style decisions—smoking, excessive drinking, unhealthy foods, and lack of exercise. But we will more often than not turn to drugs instead of a "healthy" lifestyle for a remedy. Many believe we have made extensive strides increasing support for prevention. However, funding priorities do not support that assumption. In 1988, the U.S. allocated three cents of its health dollar to fundamental public health services. That "threepence" has increased very little since then.

In tandem to the expectation of the drug development is the expectation that the drug be covered by insurance, whether or not it is efficient or medically necessary. These consumer pressures have exacerbated the mal-allocation of resources among our citizens.

This effect is further compounded by the fact that few consumers know the cost of their drugs because they are most often paid for by a third party and masked by complex pricing schemes.

The Profit Culture:

While some agree that drugs clearly improve health status, many also lament that the industry is dominated by a profit mentality and is therefore bent on making money instead of improving our health. While motives are not always clear, the claim of "profitability" is well founded. In 1998, the pharmaceutical industry ranked first on all three Fortune 500 profit indices—return on revenue, assets, and equity. The industry's median return on revenue grew by 30 percent in the 1990s and its median return on equity grew by 32 percent in the 1990s. In 1998, the drug industry's profit as a percentage of return on equity was almost 40 percent, compared to 13 percent for the rest of the Fortune 500. According to this year's Fortune 500 review, with over $20.3 billion in profits among them, pharmaceutical companies topped the automotive industry, the seven oil companies, the airlines industry, and the entertainment industry. Looking more closely at profits (percent return on revenue), the auto industry made 3.5 percent; chemicals, 5.1 percent; airlines, 5.7 percent; telecom, 11.7 percent; and pharmaceuticals, 18.6 percent—more than any other industry.[3] Here we face one of the major conundrums of this problem: How in a market-driven industry can we permit adequate return on investment (and thus encouraging future appropriate drug development), while ensuring drug affordability and availability for consumers?

High Cost of Making Drugs:

Industry leaders have associated the high cost of drugs with high manufacturing costs.

Although these costs have never been independently verified, PhRMA cites:[4]

- Total drug development time has grown from an average of 8.1 years in the 1960s to 11.6 years in the 1970s, to 14.2 years in the 1980s, to 14.9 years for drug approval during 1990-1996.

- Since 1980, the average number of clinical trials conducted prior to filing a New Drug Application (NDA) has more than doubled and the number of patients in clinical trials per NDA has increased threefold.

- The average pre-tax cost of developing a drug introduced in 1990 was $500 million, including the cost of research failures, as well as interest costs over the entire investment period.

- On average, only three out of 10 approved drugs recover average R&D costs. Companies must rely on these highly successful products to fund R&D.

- Liability costs are high.

What often is not cited in these discussions is the extent to which the federal government funds pharmaceutical research. The National Institutes of Health (NIH) spent $1 billion on drug development in 1996, but received only $27 million in royalties from the pharmaceutical industry. The federal government also subsidizes the pharmaceutical industry directly through tax credits. Between 1990 and 1996, pharmaceutical companies received $27.4 billion in income tax credits, reducing their effective tax rate to 16 percent, compared with 27 percent in other industries.[5]

Advertising:

A recent study[6] funded by health insurers has indicated that spending growth is concentrated in a few therapeutic categories that include heavily advertised drugs. In 1998, drug manufacturers spent $8.3 billion dollars promoting their products: $1.3 billion in direct-to-consumer (DTC) advertising and $7 billion detailing and advertising their products to health providers. Four categories of drugs accounted for 30.8 percent of the total $42.7 billion increase in drug spending between 1993 and 1998. These four categories include seven of the ten drugs most heavily advertised to consumers in 1998: Oral antihistamines such as **Claritin**, **Zyrtec**, and **Allegra**; antidepressants such as **Prozac**; cholesterol-reducing drugs such as **Zocor** and **Pravachol**; and anti-ulcerant drugs such as **Prilosec.** Here the question must be raised: To what extent is the public dollar subsidizing drug advertising?

Increased Volume Instead of Unit Costs:

Another recent study[7] funded by the National Pharmaceutical Council used claims data to argue that the majority of the spending increases is due to volume, not price. The industry claims that only 13 percent of increased spending is due to price increases and 87 percent is due to volume (PhRMA profile 1999). The total number of prescriptions certainly has increased, from 1.9 billion in 1993 to 2.5 billion in 1998. The newer oral antihistamines are a good example of this argument—utilization has increased 500 percent, while the price for these medications has only increased 19 percent.

Drug Pricing:

One of the most complicated aspects of drugs are the methods by which they are priced, which are determined by a highly complex system, involving numerous interactions and arrangements among manufacturers, wholesalers, retailers, insurers, PBMs, and consumers. The process is described by one analyst as "inscrutable" with the result of never knowing the real cost of the drugs or the amount discounted. In part, however, the mystery occurs because most of the data necessary to identify true manufacturing costs are deemed proprietary by the manufacturers.

Consumers, regardless of their coverage status, obtain prescription drugs through some form of retail pharmacy, including independent pharmacies, chains, pharmacies in supermarkets or mass merchandisers, and mail-order pharmacies. In 1998, sales through retail outlets accounted for 90 percent of total outpatient prescription drug sales.

As mentioned above, individuals without drug coverage and cash customers with health care coverage pay a higher price at the retail pharmacy than those who have a paid drug benefit. However, most others receive some form of discount or rebate.

In addition to lack of accurate cost data, the complexity is exacerbated by the numerous transactions in the process, e.g., manufacturers sell the drug to a wholesaler, wholesaler sells the drug to a retail pharmacy, Pharmacy Benefit Manager (PBM) negotiates discounts with a retail pharmacy, PBM negotiates rebate paid directly from the manufacturer, Medicaid receives a rebate from manufacturers, as required by law, and pharmacy sells the drug to a consumer.

Discounts can be based on a percentage discounted from the average manufacturer price (AMP), a percentage discounted from the average wholesale price (AWP), the manufacturer's "best price," or numerous other methodologies.

The result of this complexity is an inequity in pricing for consumers and a hindrance to efforts to develop sound purchasing strategies.

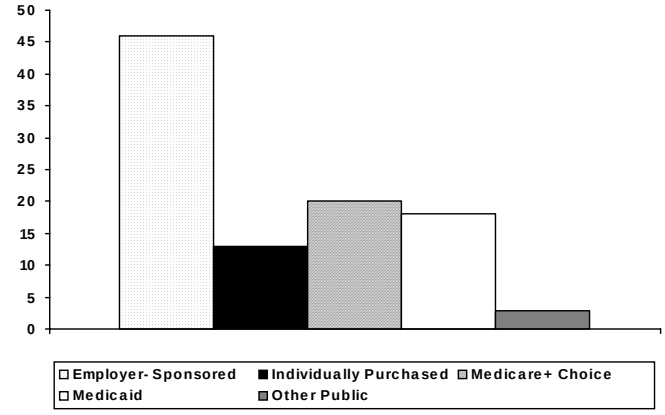
Aging Population:

One of the core factors in the increase in medication cost is increasing usage and need. The fastest growing American demographic is the elderly, a group that traditionally utilizes more health care and medication than any other age group. According to the U.S. Census, between 1998 and 2010, the 54-to-64 age group will increase by 59 percent. This group is among the higher utilizers of drugs.

Absence of Uniformity of Drug Benefits:

The most striking example is, of course, Medicare, where there is no outpatient drug coverage. In fact, one-third of Medicare beneficiaries have no drug coverage (13 million). As indicated in the figure below employer-retiree coverage has been a major source. Of the 65 percent who have some form of retiree drug coverage, almost half receive it from an employer-sponsored plan.

Figure 3: Primary Source of Supplemental Coverage
Among Medicare Beneficiaries *With* Prescription Drug Coverage, 1999
(Number of beneficiaries with some prescription drug coverage: 25.6 million)



But the HHS data (mentioned above) clearly indicates that employer-sponsored drug coverage is in decline. Although senior concerns are the major issue, it is also important to remember that 16 percent of U.S. citizens (12 percent in Washington) have no health insurance coverage at all, with 25 percent of all non-Medicare population with no drug coverage.

This problem most likely will worsen as employers, wanting to be relieved of benefit design and management and exposure to liability, move from a defined benefit to a defined contribution. In its most unfettered form, this merely gives employees (individually) a certain amount of money, and they must find their own coverage. This will be a particular burden on employees between the ages 50 and 64, who will find it difficult to find affordable coverage in the individual market.

The uniformity issue not only affects who is covered and for how much, but also what drugs are covered. Here, the most glaring deficiencies are in the areas of women's health and mental health.

Lack of Demand or Disease Management:

Many would argue that today's concept of "Managed Care" is really a euphemism for cost controls through risk-based contracting. However, managed care's original promise centered on a vision of moderating demand for unneeded care and carefully coordinating and managing needed clinical interventions that would efficiently and effectively manage illnesses in enrolled populations. This vision has re-emerged in recent years in a field coming to be known as "demand and disease management."

Demand management programs focus largely on modifying patients' demand for medical interventions through social marketing, patient self-care information, telephone consultations with specially trained nurses and other personnel and by other means.

Disease management is a population based, clinical approach that employs evidence-based medical and behavioral care. Disease managers identify patients within a health plan's enrolled population that have a disease such as diabetes, where research has found that carefully coordinated clinical management and patient behavior change can lower medical costs and improve patient outcomes. A patient care information system is developed that identifies and tracks patient care and patient behavior against carefully constructed, evidence-based clinical protocols. Treatment teams are trained and include clinical specialists, health educators and others. Management incentives are developed and any administrative barriers to full implementation of treatment protocols are removed. Patient progress and overall system costs are tracked and reported.

Disease management has been widely promoted in recent years by pharmaceutical manufacturers as a marketing scheme. For example, a manufacturer might market a disease management protocol for high cholesterol that involves regular physician visits, some dietary advice and on-going prescriptions of their cholesterol-reducing drug. Such marketing schemes have fueled the development and proliferation of disease management programs and strategies, even though evidence of their effectiveness is less than abundant.

Still, many simple demand management strategies, such as the distribution of patient information books on treating common, minor health complaints. These plans have documented significant savings and improved health outcomes.

Disease management interventions, often involving the use of drugs in combination with regular clinical contact and patient support and education, have been proven effective in improving patient outcomes and containing costs in relation to diabetes, asthma, heart disease, depression, and many other prevalent illnesses in managed care enrolled populations.

And yet most managed care plans do not offer many well-developed demand or disease management programs. Significant impediments to the proliferation of these programs include their need for up-front investment to create or adapt clinical protocols and other tools, staff training issues, the lack of adequate data systems, and the poor coordination between clinicians, health educators, and various other medical specialists who need to function as a team to make disease management programs work effectively.

Lack of Accurate Drug Information:

Although there appears to be a plethora of health information available today, especially on the Internet, many citizens remain uninformed about their drugs. They are often unclear about what drugs are covered by their plan, what they must pay, and the method used by their insurers to add or remove drugs from the formulary.

Further, few consumers have access to understandable information about drug selection which they can use to analyze the D-T-C sources. It is interesting to note that even some providers complain about the lack of information on drug effects.

Lack of sound information has been of increased interest due to recent studies on medical errors. Although serious errors on drugs mostly lie with the provider or hospital, many consumer mistakes are also dangerous.

Everyone should know the answers to the following questions before taking any drugs.

1. What are the brand and generic names of the medication?
2. What does it look like?
3. Why am I taking it?
4. How much should I take, and how often?
5. When is the best time to take it?
6. How long will I need to take it?
7. What side effects should I expect, and what should I do if they happen?
8. What should I do if I miss a dose?
9. Does this interact with my other medications or any foods?
10. Does this replace anything else I was taking?
11. Where and how do I store it?

Although the private sectors clearly play a role in educating consumers, there is also a role for government here to ensure that consumer health information is comprehensive, accurate, and readily available.